

**REMARKS**

Claims 44-58 are pending. Claims 51-58 were withdrawn and are now canceled. Claims 44 and 48 have been amended. Reconsideration of the pending claims is requested.

**Status of Prosecution**

Applicants thank the Examiner for the courtesy shown in during the telephone call received from the Office on April 29, 2004 indicating that this first substantive action on the merits in this case should have been designated as a “non-final” action. In view of these facts, Applicants will consider this Office Action to be “non-final”.

**Interference Remarks**

Applicants acknowledge the Office’s position regarding the possibility of an interference with co-pending applications related to WO 00/20590, such as 09/167219.

**Continuation Data**

Applicants acknowledge the amendment made to the claim for priority filed in the preliminary amendment of December 14, 2001, which indicates that the parent U.S. provisional patent application of this line of patent application has now lapsed.

**Biological Deposit**

Claim 46 was rejected under 35 U.S.C. § 112, first paragraph, because the deposit information regarding Accession No. PTA-312 was allegedly defective. 37 CFR § 1.809(d) requires that, for each deposit made, the specification shall contain 1) the accession number for the deposit; 2) the date of deposit; 3) a description of the deposited material; and 4) the name and address of the depository. The specification has been amended to recite the name and address of the depository. A copy of the deposit receipt is enclosed with this Amendment. The receipt contains the viability and availability information requested by the Office. Applicants submit that the amendment to the specification and the provided copy of the deposit receipt meets Applicants’ duties as described in 37 CFR §§ 1.801-1.809. As such, withdrawal of this rejection is requested.

The pending claims were in possession of Applicants at the time the application was filed.

Claims 44 and 47-50 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly reciting subject matter that was not adequately described in the specification to permit one of ordinary skill in the art to reasonably conclude that Applicants were in possession of the claimed subject matter at the time the application was filed. Specifically, the Office has alleged that the specification as filed does not support a recombinant nucleic acid encoding a polypeptide at least 90% identical to the amino acid sequence of SEQ ID NO: 2. Applicants respectfully disagree.

“[I]psis verbis disclosure is not necessary to satisfy the written description requirement of section 112. Instead, the disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question.” *Fujikawa v. Wattanasin*, 93 F.3d 1559, 39 USPQ2d 1895 (Fed. Cir. 1996). In the present case, Applicants have disclosed an amino acid sequence and seek to protect a range of variants containing conservative amino acid substitutions. One of ordinary skill in the art would reasonably conclude that Applicants were in possession of this subject matter when reading the specification, especially page 27, lines 1-23, which discusses conservative substitutions and variants contemplated by the present application.

Solely to advance the prosecution of the present case, however, Applicants have amended the claim to recite only the sequence identification number of the desired subject matter. Applicants reserve the right to pursue the subject matter of the variants in a continuation or divisional filing.

Claims 44 and 47-50 are fully supported by an enabling disclosure

The Office rejected claims 44 and 47-50 under 35 U.S.C. § 112, first paragraph, for allegedly reciting subject matter that was not enabled by the present specification. Specifically, the Office alleged that, while being enabled for a polynucleotide of SEQ ID NO: 1 or a polynucleotide encoding SEQ ID NO: 2, did not enable sequences at least 90% identical to these sequences.

“To be enabling, the specification of a patent must teach those skilled in the art to make and use the full scope of the claimed invention without ‘undue experimentation’ ... Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples.” *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993).

Applicants respectfully submit that the pending claims are fully supported by an enabling disclosure. The Office seems to be arguing that because Applicants did not explicitly disclose sequences that are at least 90% identical to the sequences of interest, Applicants are somehow not entitled to this subject matter. As stated above, there is no *ipsis verbis* requirement in section 112. For enablement, all that is required is that one of ordinary skill in the art be able to make and use the claimed invention without undue experimentation. Here, the skilled artisan would readily be able to look to the disclosed sequences and make changes to 10% of the amino acids in the sequence such that the resulting sequence would be at least 90% identical to the disclosed sequences and the variant so generated would only possess conservative amino acid substitutions. The fact that a large number of variants are contemplated and encompassed by the claim language is irrelevant here since the specification, taken with the general level of knowledge existing in the art, would be sufficient to allow one to practice the claimed invention without undue experimentation.

Nevertheless, solely to advance the prosecution of the present case, Applicants have removed the “at least 90% identity” language from the pending claims. As such, the present rejection of the claims has been obviated.

The subject matter of Claim 48 is fully supported by an enabling disclosure.

The Office further alleged that even if Applicants were to overcome the rejections of the pending claims under section 112, that the subject matter of claim 48 would still be rejected for allegedly not being enabled. The Office argues that the term “recombinant host cell” is not defined in the specification. The Office has interpreted the language of claim 48 as reading on a host cell *in vivo* that comprises a recombinant nucleic acid encoding the claimed subject matter. The Office characterized this hypothetical situation as a product of “gene therapy” and then proceeds to discuss references almost ten years old or in some cases older, that detail the difficulties in practicing “gene therapy.”

Applicants respectfully disagree with the Office regarding the basis of the present rejection and the allegations made regarding gene therapy. Nevertheless, solely to advance prosecution of the present case, claim 48 has been amended to recite a host modified to contain a claimed nucleotide sequence. One of ordinary skill in the art would readily be able to construct a vector containing the

claimed sequence, introduce that vector into a host cell, and elicit protein expression from that vector using the teachings provided in the specification and the general level of information available in the art at the time the application was filed. As such, the subject matter of claim 48 is fully supported by an enabling disclosure. Accordingly, Applicants request that the present rejection of this claim be withdrawn.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket **No. 511582002410**.

Dated: May 17, 2004

Respectfully submitted,

By 

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## BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

### INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3  
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

UroGenesys, Inc.  
Attn: Donald B. Rice  
1701 Colorado Avenue  
Santa Monica, CA 90404

Deposited on Behalf of: UroGenesys, Inc.

Identification Reference by Depositor:

Patent Deposit Designation

<i>Escherichia coli</i> strain DH10B carrying recombinant plasmid p98P4B6-GTD3	PTA-311
<i>E. coli</i> strain DH10B carrying recombinant plasmid p101P3A11	PTA-312

The deposits were accompanied by:      a scientific description X a proposed taxonomic description indicated above. The deposits were received July 2, 1999 by this International Depository Authority and have been accepted.

AT YOUR REQUEST: X We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested July 9, 1999. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

  
Barbara M. Hailey, Administrator, Patent Depository

Date: July 9, 1999

cc: Kenneth K. Sharples (Ref. Docket 1703-011 and 1703-043)